IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 09-037 (RBK)(JS) CONSOLIDATED REDACTED - PUBLIC VERSION
SHIONOGI, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. MYLAN, INC., and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 10-135 (RBK)(JS)

PLAINTIFF SHIONOGI INC.'S REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND RECALL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

RULES AND STATUTES

OTHER AUTHORITIES

I. INTRODUCTION

On September 30, 2011—[redacted]

Lupin's Opposition to Shionogi's motion asserts newly minted non-infringement and invalidity positions that Lupin never disclosed in its contentions, as this Court's local patent rules require—contentions that Lupin served over one year ago and never amended. However, Lupin's sandbagging strategy fails because its "gotcha" arguments are legally and factually wrong: Lupin incorrectly and improperly disavows its FDA-approved label, contradicts its own claim construction positions and the Court's claim construction Order, and misrepresents explicit action taken by the Patent Office. Immediate and emergency relief from the Court—[redacted]—is warranted, and nothing in Lupin's last-minute, manufactured, and misleading arguments establishes the contrary.[2]

[1] Declaration of Brian A. Sutherland ("Sutherland Decl."), Ex. 8 at LUP 0065762.

[2] Lupin's newly asserted positions were not disclosed until last week, resulting in prejudice to Shionogi. Lupin should have detailed these arguments in its contentions as required by the local patent rules. *See* N.J. Patent L.R. 3.6 and 3.7. For that reason, the Court should reject and strike all arguments not found in Lupin's non-infringement and invalidity contentions. *See Venetec Int'l, Inc. v. Medical Device Group, Inc.*, No. 06CV83, 2007 WL 2238475, at *4 n.2 (S.D. Cal. Aug. 3, 2007) (court has authority to "grant summary judgment of non-infringement where plaintiff fails to comply with the local rule on amending final non-infringement contentions and submits arguments in opposition to summary judgment that are inconsistent with those contentions"); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 2006 U.S. Dist. LEXIS 3539, at *23 (D.N.J. Jan. 31, 2006) (striking defendant's non-infringement defense because it was raised late without justification, causing "at least some prejudice" to plaintiff).

II. ARGUMENT

A. Shionogi is Likely to Succeed on the Merits of Its Claims

Lupin has no legitimate non-infringement position. Instead, it argues, remarkably, that its FDA-approved label—designed to inform the public how its drug actually works—does not accurately reflect the properties of its product. In so doing, Lupin relies on [redacted] and on a claim construction position it *never advanced before* and that is contrary to this Court's Order construing the terms of the '866 patent. Lupin's invalidity position is even weaker, relying on a mischaracterization of the prosecution history to suggest that the asserted claims of the '866 patent were not allowed by the Patent Office and are not entitled to a presumption of validity. Lupin is wrong. The Patent Office indisputably determined these claims to be valid over the same prior art that Lupin now uses to rehash grounds already considered and rejected by the Patent Office.

As Shionogi's Opening Brief demonstrates, it is likely to prevail on the merits: Lupin's generic copy of FORTAMET meets, and therefore infringes, each limitation of claims 1, 3-5 and 25 of the '866 patent, and Lupin is not likely to succeed in proving invalidity. (*See* D.I. 206, Opening Br. at 11-22.) Lupin's Opposition does not present any legitimate argument or evidence leading to a contrary conclusion.

B. Lupin's Product Infringes the '866 Patent

1. Lupin's FDA-Approved Label is Conclusive Evidence of Infringement

Lupin's Opposition ("Opp."), like its non-infringement contentions, [redacted]

[redacted] However, Lupin's FDA-approved product label *explicitly states* that Lupin's metformin extended-release tablets have, as the asserted claims of the '866 patent require, a mean T_{max} of 6 hours when administered after dinner. (D.I. 207, Noyes Decl., Ex. 2 at LUP 0065441; D.I. 210, Fleckenstein Decl. ¶ 53.)

According to controlling Federal Circuit precedent, where a generic label "defines a property of a [generic product] such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that limitation." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (granting summary judgment of infringement based on label). Lupin's product label—also referred to as the package insert—defines its generic copy of FORTAMET as having a T_{max} that meets the claim limitations. The label is therefore conclusive evidence that Lupin's generic product infringes the '866 patent, and that Shionogi is likely to prevail on infringement. *See id.* ("[A]n ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.").[3] Lupin's argument to this Court is thus contrary to clear, and binding, precedent.

In each of these cases, the court expressly rejected the same argument Lupin makes here—that because it was required to copy the label it should not be held liable for infringement. *See TorPharm, Inc.*, 300 F.3d at 1374 n.2; *Research Found.*, 723 F. Supp.

[3] *See also Research Found. of State Univ. of N.Y. v. Mylan Pharms. Inc.*, 723 F. Supp. 2d 638, 647 (D. Del. 2010) (granting preliminary injunction and holding that "it is entirely proper to rely on the statements in [a generic's] label"); *Ranbaxy Labs. Ltd. v. Abbott Labs.*, No. 04 C 8078, 2005 WL 3050608, at *14-15 (N.D. Ill. Nov. 10, 2005) (granting preliminary injunction and holding that "the plain language of claim 6 is met by [generic's] proposed package insert").

2d at 647; *Ranbaxy Labs. Ltd.*, 2005 WL 3050608, at *15; *cf. Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-50 (Fed. Cir. 2000) (relying on generic's ANDA as evidence of non-infringement). Lupin's attempt to walk away from its own label should likewise be rejected.[4]

The Supreme Court's ruling in *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011), on which Lupin relies heavily, does not suggest otherwise, nor does it abrogate the authority cited above. The question of whether a generic label constitutes evidence of patent infringement was not presented in *Pliva* at all; rather, the Court decided whether FDA regulations preempted an alleged state law duty to provide certain warnings on generic drugs. 131 S. Ct. at 2572. In holding that a generic manufacturer could not, post-approval, unilaterally add warnings to its label inconsistent with that of the branded drug, the Court said nothing about whether statements of fact in a generic label make the existence of such facts "more probable or less probable." Fed. R. Evid. 401. Therefore, even after *Pliva*, there can be no dispute that Lupin's label is controlling evidence that its generic copy of FORTAMET meets the T_{max} limitation of the claims, and therefore, infringes.[5] *See TorPharm*, 300 F.3d at 1373.

[4] In addition to being rejected by the Federal Circuit, Lupin's assertion that it had no choice but to copy Shionogi's label is incorrect. Lupin could have sought approval for changes required because of alleged differences in pharmacokinetics (*e.g.*, T_{max}). *See* 21 C.F.R. § 314.94(a)(8)(iv); *cf. Zeneca Inc. v. Shalala*, No. CIV.A. WMN–99–307, 1999 WL 728104, at *10 (D. Md. Aug. 11, 1999). It did not. Lupin's decision to instead copy Shionogi's label *verbatim* and to adopt its statements that the T_{max} of the "metformin hydrochloride extended-release tablets" is within the range claimed by the '866 patent — is controlling evidence that Lupin's generic copy of FORTAMET has a mean T_{max} within the claimed range.

[5] The Supreme Court in *Pliva* most assuredly did not adopt Lupin's bizarre argument that generic companies are excused from their statutory duty to refrain from making misleading and false statements in a product label. Indeed, the law (not surprisingly) is directly to the contrary. *See* 21 C.F.R. § 314.150(b)(3); *id.* § 314.150(a)(2)(iv). A "proposed label must be truthful and accurate; the proposed label is submitted to the FDA under penalty of perjury." *Research Found.*, 723 F. Supp. 2d at 647.

Lupin also tries to distinguish the "steady state" study disclosed in Table 1 of its FDA-approved label (showing a mean T_{max} of 6 hours) by arguing—again for the first time—[redacted] (Opp. at 18.) Lupin's argument is directly contrary to this Court's construction of that term: "single dose" means "the amount of the drug administered to a human patient at one time." (*See* D.I. 191 at 12.) Now, Lupin argues (in a footnote) that [redacted] (*See* Opp. at 18, n.15.) As a result, according to Lupin, [redacted] (*Id.* at 18.)

However, during claim construction, Lupin never suggested that [redacted].[6] Nor could it. The '866 patent is directed to a dosage form for the chronic treatment of diabetes—through once-a-day dosing—and not just a one-time administration. (Noyes Decl., Ex. 4.) As the Court recognized, "the claims themselves include the concept of 'once-a-day' dosage." (D.I. 191 at 13.) Indeed, the asserted claims recite a "dosage form . . . ***suitable for providing once-a-day oral administration of a single dose*** . . . ." (*See* Noyes Decl., Ex. 4, '866 patent at 21:53-57 (emphasis added).) The requirement of "once-a-day" administration proves that the claims cover multiple daily (once-a-day) administrations to reach, and to maintain, a

[6] To the contrary, Lupin agreed with Shionogi that "single dose" has the plain and ordinary meaning of "the amount of the drug administered to a human patient at one time" – and also urged the Court to adopt this meaning. (*See* D.I. 96, Lupin's Revised Claim Construction And Prehearing Statement at 7; D.I. 150, Lupin's Opening Claim Construction Brief at 15.) Nothing in that agreed construction limits the claims in the way Lupin now suggests. Indeed, Defendant Mylan expressly argued in the claim construction briefing that the term "single dose" meant "administering a dosage of the drug to a single patient at one time in a single dosage interval." (D.I. 149, Mylan's Opening Claim Construction Brief, at 17-19.) Lupin did not join in that construction, which this Court likewise rejected.

steady state of the drug.[7]

Moreover, Lupin's argument also must fail because its own label expressly states that its generic product has a T_{max} of 6.1 when administered *in a single dose study*. (*See* Noyes Decl., Ex. 2, at LUP 0065441; *see also* Fleckenstein Supp. Decl. ¶ 62.) Finally, it is irrelevant whether studies reporting T_{max} were performed with patients in a steady state or simply after those patients were given a single dose because the results would be similar. (*See* Fleckenstein Supp. Decl. ¶ 61.) In fact, Lupin's own label demonstrates such studies produce similar (even nearly identical) results (*i.e.*, T_{max} of 6 hours in the steady state study versus T_{max} of 6.1 hours in the single dose food effect study). (Noyes Decl., Ex. 2 at LUP 0065441.)

2. [redacted]

[7] Over the treatment period using a dosage form according to the '866 patent, a steady state is reached, meaning that the peaks and valleys of drug in the plasma are relatively predictable. (*See* Supplemental Declaration of Dr. Lawrence L. Fleckenstein ("Fleckenstein Supp. Decl.") at ¶ 61.) When a patient takes the drug in the steady state, the level of drug will increase in the plasma and reach T_{max} in much the same way as a patient taking the drug for the first time. Each time the patient takes the drug, she is taking the drug as a "single dose."

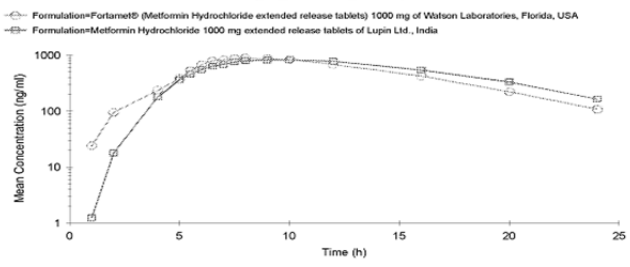
[redacted]

[8] [redacted]

[redacted]

Figure 1

Semi-log and Linear Plot of Mean Plasma Metformin Concentrations versus Time Profiles in Healthy Human Adult Subjects



[redacted]

[redacted]

C. **Lupin Cannot Satisfy Its Burden of Proving Invalidity**

Shionogi's Opening Brief demonstrates that Lupin cannot meet its heavy burden of showing, by clear and convincing evidence, that the asserted claims of the '866 patent are invalid, at least because the prior art Lupin cites was already considered by the Patent Office and the claims determined patentable over that prior art. (*See* Opening Br. at 19-22.) Apparently acknowledging that it cannot meet this burden, Lupin resorts to another never-before-disclosed argument. It now contends that the "claims which Shionogi asserts against Lupin ***were actually disallowed by the PTO examiner as obvious over the prior art***." (*See* Opp. at 1, 22 (emphasis added).) Yet, Lupin *never* made this argument in its invalidity contentions or at any time during claim construction. Most importantly, this argument is demonstrably wrong. ***All of the asserted claims of the '866 patent were allowed and issued*** by the Patent Office over the prior art, as Lupin's own patent law expert is forced to admit. (*See* D.I. 237, Steiner Decl. ¶ 33 ("claims 1, 4, 5, 7 through 27, and 29 were allowed …").

In any event, Lupin cannot overcome the fact the Patent Office already considered the very prior art that Lupin now asserts, and then *allowed and issued* the asserted claims. This Court need not re-evaluate the expert determination of the Patent Office to conclude

that Lupin is unlikely to carry its heavy burden of establishing invalidity in this case.

1. **The Claims of the '866 Patent are Presumed Valid**

Lupin's argument is based on a selective (and misleading) misreading of the prosecution history of the '866 patent. During prosecution, the Patent Office initially rejected the claims of the '866 patent over prior art teaching formulations having a T_{max} of ***8 hours*** or longer—a range the asserted claims do not cover. (*See* Steiner Decl. ¶¶ 26-31.) However, after a November 20, 2003 interview, the Patent Office concluded—based on the arguments presented by the applicants' attorneys—that "the closest prior art [taught] a T_{max} of 8 hours" and *not* the claimed ranges of 5.5 to 7.0 and 5.5 to 7.5 hours. (*See* Sutherland Decl., Ex. 3, '866 Patent File History, November 21, 2003 Response to Office Action at AND0000272.) The Patent Office also agreed that a T_{max} range of 5.5 to 7.0 hours (found in asserted claim 3 of the '866 patent) ***was patentable*** over the prior art, and "further agreed to consider the patentability of the broader range to 7.5 hours [in issued claim 1] if applicants were [to] provide a working example of that value." (*Id.*) Less than one month later, on December 19, 2003, ***the Patent Office allowed all of the claims that issued in the '866 patent***, including claims to dosage forms with a T_{max} range of up to 7.5 hours. (*See id.*, Ex. 2, '866 Patent File History, December 19, 2003 Notice of Allowance at AND0000278.) The Patent Office made this allowance based on the "interview conducted on 11/20/03." (*Id.*)

Lupin's Opposition fails to acknowledge that the Patent Office allowed all of the asserted claims of the '866 patent, and that, as a result, the presumption of validity applies.[10] *Al-Site Corp. v. USI Int'l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) ("The

[10] Apparently recognizing the weakness of its position, Lupin seeks to recast the interview summary as proving that "the T_{max} value to 7.5 hours [recited in issued claim 1], [was] too

presumption of validity under 35 U.S.C. § 282 carries with it a presumption that the Examiner did his duty and knew what claims he was allowing."). Instead, Lupin focuses on a technicality arising from Patent Office procedure. However, this technicality—one that resulted in the applicants, and *not* the Patent Office, attempting to cancel claim 1 for reasons unrelated to prior art—cannot vitiate the presumption of validity.[11]

Notwithstanding the procedural history of the prosecution, ultimately (and most importantly), the '866 patent issued with claim 1 and the T_{max} range of 5.5 to 7.5 hours—a claim the Patent Office explicitly allowed. Lupin's only response is to ignore this allowance and wrongly state that "none of the claims were ultimately allowed." (*See* Opp. at 20; *see also* Steiner Decl. ¶ 12.) Even if this were true (and it is not), it is

---

close to the 8 hours of the prior art for the examiner to be willing to allow." (*See* Opp. at 22.) This contention is flatly contradicted by the Patent Office's Notice of Allowance filed less than one month later that allowed all the claims at issue *based on the interview.* (*See* Sutherland Decl., Ex. 2,'866 Patent File History, 12/19/2003 Notice of Allowance.) Far from being "too close" to the prior art, the Patent Office decided that the claims were patentable.

[11] More particularly, pursuant to Patent Office rules, the applicants of the '866 patent were required to submit a response to a May 21, 2003 rejection of the asserted claims *just one day* after their Patent Office interview on November 20, 2003. Had the applicants failed to respond by November 21, 2003, their patent application would have been abandoned. *See* 35 U.S.C. § 133; *see also* Sutherland Decl., Ex. 9, May 21, 2003 Office Action at AND0000253 (noting that failure to respond within six months "will, by statute, cause the application to become ABANDONED" (emphasis in original)). To avoid abandonment, the applicants filed the required response, in which they (not the Patent Office) purportedly cancelled claim 1 "in view of the deadline for filing the response." The applicants did not seek to cancel claim 1 because it was unpatentable over the prior art. (*See* Sutherland Decl., Ex. 3, November 21, 2003 Response to May 21, 2003 Office Action at AND0000272; *id.*, Ex. 1 (fax cover sheet and transmittal form for November 21, 2003 Response).)

On January 7, 2004, the applicants' attorneys and the Patent Office discussed the November 21, 2003 response and "determined that certain claims that were indicated as ***allowable*** were cancelled ([issued claim 1] and 4)." (*See id.*, Ex. 4, January 8, 2004 Communication.) The Patent Office then issued a Supplemental Notice of Allowance on November 15, 2004 deleting claim 1 from the allowed claims. (*See id.*, Ex. 5, at AND0000305.) In other words, the applicants—not the Patent Office—cancelled claim 1 for procedural reasons unrelated to its patentability. Lupin's representation to this Court that claim 1 was "***actually disallowed by the PTO examiner as obvious over the prior art***" is just not true. (*See* Opp. at 1, 22 (emphasis added).)

irrelevant. The Patent Office determined that all of the claims at issue, including claim 1, were allowable over the prior art. (*See* Sutherland Decl., Ex. 2, '866 Patent File History, December 19, 2003 Notice of Allowance at AND0000278.) As a result, the presumption of validity applies to the asserted claims. *See Al-Site Corp*, 174 F.3d at 1323; *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996) (presumption of validity based on presumption of administrative correctness of actions by agency charged with examination of patentability). There is no law to the contrary. Indeed, Lupin and its patent law expert have cited to no Patent Office rule, statutory provision, or case law requiring the Court to ignore the clear evidence that the claims at issue were allowed over the prior art.[12]

To the contrary, Lupin's attempt to avoid the presumption contradicts well-settled law. The Federal Circuit has made clear that the presumption of validity "is *never* annihilated, destroyed, or even weakened, regardless of what facts are of record." *See ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (emphasis in original). The Supreme Court unanimously affirmed the unwavering strength of the presumption. *See Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238, 2246 (2011). Lupin cannot avoid the presumption of validity based on a procedural technicality, especially where the claims at issue indisputably were allowed over the prior art.[13]

---

[12] Mr. Steiner provides a very detailed discussion of the examination process. (*See* Steiner Decl. ¶¶ 15-24.) In this detailed discussion, Mr. Steiner does not point to a single provision in the rules or law that indicates the claims at issue were rejected by the Patent Office over the prior art.

[13] The cases cited by Lupin regarding the correction of claims are inapposite. *Group One, Inc.* relates to the correction of a claim that was invalid on its face due to an omission of a necessary element. *See Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1302 (Fed. Cir. 2005). *Novo Industries* discussed when a district court may correct a patent.

For these reasons, the claims of the '866 patent are entitled to the presumption of validity. Shionogi is entitled to assert these claims because they were allowed over the prior art and issued by the Patent Office. (*See* Sutherland Decl., Ex. 2, '866 Patent File History, 12/19/2003 Notice of Allowance at AND0000278.) Lupin has cited no rule or case law preventing Shionogi from asserting these valid and issued claims.[14]

2. **Lupin's Prior Art Does Not Invalidate the '866 Patent**

Regardless of Lupin's belated, hyper-technical argument, the simple fact remains that the asserted claims of the '866 patent were issued by the Patent Office, and they are entitled to a presumption of validity. To overcome that presumption, Lupin must demonstrate invalidity by clear and convincing evidence. *See Microsoft*, 131 S. Ct. at 2242. Lupin cannot make, and has not made, this showing.

As detailed in Shionogi's Opening brief, the prior art Lupin cites does not and cannot invalidate claims of the '866 patent. (Opening Br. at 19-22.) Like its invalidity contentions, Lupin's Opposition merely resurrects the same arguments raised by the Patent Office, and overcome by the applicants. (*Id.* at 20-22.) Both of the primary references cited by Lupin (Timmons and Cheng) were discussed in the '866 patent specification, and Cheng was extensively discussed during prosecution. Because Lupin relies ***entirely*** on prior art already considered by the Patent Office during prosecution – art that the applicants overcame – Lupin has an "added burden" to meet the already heavy burden of showing invalidity. *See PharmStem Therapeutics v. Viacell, Inc.*, 491 F.3d

---

Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348 (Fed. Cir. 2003). Neither case is relevant here because the claims at issue were allowed over the prior art and issued by the Patent Office.

[14] In any event, the applicants attempted to only cancel claim 1. The applicants did not attempt to cancel any of the other presently asserted claims.

1342, 1366 (Fed. Cir. 2007); *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1378 (Fed. Cir. 2006). Lupin cannot meet this burden. As a result, because "[Lupin] fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies [Shionogi's] burden on validity." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001).

D. [redacted] Lupin asserts that Shionogi "delayed in seeking injunctive relief and took no steps to protect itself" from Lupin's [redacted] (Opp. at 3.) This assertion ispatently wrong. [redacted]

[15] Lupin argues that two Wall Street Journal articles should have [redacted] Those articles are, at best, vague. For example, the September 28, 2011 article simply states "[i]n ***the next few months Lupin could launch*** copies of Pfizer Inc.'s antipsychotic drug Geodon and Andrx Labs LLC's Fortamet for diabetes, Mr. Swaminathan said." (D.I. 231, Brauerman Decl. Ex. 9.) (emphasis added) Certainly, this statement does not suggest a launch was imminent, or even probable. [redacted]

[redacted] (*See* Opp. at 23-30.) Lupin is wrong for at least five reasons. [redacted] (*See id.* at 27.) Lupin responds, without support, that Shionogi's loyal base of FORTAMET consumers is not particularly "sensitive to price" because any price-sensitive consumers would already "have switched to one of the generic metformin extended release products." (Opp. at 29.) But this claim ignores the high probability that [redacted] (*See* Vellturo Supp. Decl. ¶¶ 16-17.)

[redacted]

[redacted] *See Sanofi-Aventis Deutschland GmbH v. Glenmark Pharma. Inc.*, USA, No. 07-CV-5855 (DMC-JAD), 2011 U.S. Dist. LEXIS 112507, at *27 (D.N.J. Sept. 30, 2011) (granting motion for permanent injunction and noting "lost sales standing alone are insufficient to prove irreparable harm because they are presumed compensable through money damages; but, when viewed in conjunction with other injuries, lost sales can be a factor in the irreparable injury calculation." (internal quotation marks omitted).

[redacted]

[redacted]

[16] Lupin relies on *Graceway Pharms., LLC v. Perrigo Co.*, 722 F. Supp. 2d 566, 578 (D.N.J. 2010), for the proposition that Shionogi must [redacted] No such holding is found in that opinion. In *Graceway*, plaintiff claimed current and future price erosion, but then failed to rebut defendant's assertion that plaintiff had increased the price of the branded product after the generic entered the market. *See id.* at 577-78. The Court also held that plaintiffs were "not likely to succeed on the merits" given defendants' "strong showing of obviousness." *Id.* at 572, 575.

[17] Lupin's related contention [redacted] is baseless. Opp. at 26-27; *see* (Vellturo Supp. Decl. ¶¶ 18-21.) Plavix – whose manufacturer, Sanofi, succeeded in obtaining a preliminary injunction upon, *inter alia*, a showing of irreparable harm, *see Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006) – dominates, by a wide margin, its market. (Vellturo Supp. Decl. ¶ 19.) In stark contrast, [redacted] (*Id.* ¶ 20.) In any

[redacted]

Finally, Lupin argues that "all of the harm which Shionogi claims has befallen it as a result of generic competition[] will continue even if Lupin is enjoined, because [Andrx's] authorized generic will create the same problems." (Opp. at 28.) But Lupin's entry will have caused this harm to Shionogi, and Lupin should not be heard to argue that it should benefit from the result of its actions. Moreover, this argument assumes too much. Andrx has not entered the market, and may not. (*See* Melloy Decl. ¶ 24; Vellturo Supp. Decl. ¶ 7.) [redacted]

E. [redacted]

event, many courts have found a likelihood of irreparable harm based on the plaintiff's probable inability to re-gain its position in the market absent injunctive relief. (*See* Opening Br. at 22-23 (citing cases).)

Sutherland Decl., Ex. 8, LUP 0065762), Lupin, a large pharmaceutical company which is "ranked fifth by prescriptions in the United States" (Opp. at 3), decided to target a much smaller company. (Vellturo Supp. Decl. ¶ 31.) And while FORTAMET is not Shionogi's only product, it accounted for nearly [redacted] of Shionogi's total profits in 2010. (Melloy Decl. ¶ 14.) [redacted]

More fundamentally, Lupin ignores the fact that any harm it allegedly will suffer if the Court grants injunctive relief was foreseeable to it and "the result of [Lupin's] own calculated risk to launch its product prejudgment." *Sanofi-Synthelabo*, 470 F.3d at 1383 (affording little weight to potential harm of generic's own making). Indeed, Lupin fails to even acknowledge the authority cited in Shionogi's Opening Brief that self-made hardships must be discounted in the balancing process. *See Ortho McNeil*, 2009 WL 2182665, at *11 ("this hardship is solely of Barr's own making"); *see also Sanofi-Aventis Deutschland*, 2011 U.S. Dist. LEXIS 112507 (granting permanent injunction and finding that harms stemming from defendant's generic launch while case was pending were of its own making). [redacted]

As to the irreparable harm Lupin claims it will suffer – loss of customer goodwill

– Lupin fails to satisfy its own asserted standard. (*See* Opp. at 28 (arguing, with respect to Shionogi, that "in the absence of proof, unsupported claims and speculations" of potential injury to goodwill should be disregarded).) Indeed, Lupin has taken the position that information regarding its own customers is "irrelevant" to this motion. (*See* D.I. 241, Letter from Stephen B. Brauerman to Hon. Robert B. Kugler, dated Oct. 20, 2011 ("Lupin's pricing data, sales volume, rebate and discount data, marketing plans, shipment information, customer names, and customer contracts … is simply not relevant to the issues presented by Shionogi's motion for a preliminary injunction …").

F. [redacted]

III. CONCLUSION

For the reasons set forth above and in Shionogi's Opening Brief, the Court should grant Shionogi's motion, enter a preliminary injunction against Lupin, and [redacted]

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiff Shionogi

OF COUNSEL:

Christopher R. Noyes
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 626-6000

David A. Manspeizer
David B. Bassett
Peter Shen
WILMER CUTLER PICKERING HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

October 24, 2011
4559853.3

CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2011, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

Richard Herrmann, Esquire
Mary B. Matterer, Esquire
MORRIS JAMES LLP

I also certify that copies were caused to be served on October 31, 2011, upon the following in the manner indicated:

Richard D. Kirk, Esquire — *VIA ELECTRONIC MAIL*
Stephen B. Brauerman, Esquire
BAYARD, P.A.
222 Delaware Avenue – Suite 900
Wilmington, DE 19801
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

D. Christopher Ohly, Esquire — *VIA ELECTRONIC MAIL*
SCHIFF HARDIN LLP
1666 K Street, N.W.
Washington, DC 20006
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Douglass C. Hochstetler, Esquire — *VIA ELECTRONIC MAIL*
Sailesh K. Patel, Esquire
SCHIFF HARDIN LLP
6600 Sears Tower
Chicago, IL 60606
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beth D. Jacob, Esquire — *VIA ELECTRONIC MAIL*
SCHIFF HARDIN LLP
900 Third Avenue – 23rd Floor
New York, NY 10022
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Richard Herrmann, Esquire — *VIA ELECTRONIC MAIL*
Mary B. Matterer, Esquire
MORRIS JAMES LLP
500 Delaware Avenue – Suite 1500
Wilmington, DE 19801
Attorneys for Mylan Inc. and Mylan Pharmaceuticals Inc.

Timothy H. Kratz, Esquire — *VIA ELECTRONIC MAIL*
Robert L. Florence, Esquire
George J. Barry III, Esquire
MCGUIRE WOODS LLP
1170 Peachtree Street
Suite 2100
Atlanta, GA 30309
Attorneys for Mylan Inc. and Mylan Pharmaceuticals Inc.

/s/ Karen Jacobs Louden
_____
Karen Jacobs Louden (#2881)